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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,226	08/19/2003	Ashley I. Bush	0609.4810002	3164

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EXAMINER	
DUTT, ADITI	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
06/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,226	BUSH ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 22 March 2007 has been entered into the record and has been fully considered. Claims 36 and 37, are amended. Claims 1-35 and 38 are canceled.

2. Claims 36 and 37, are pending in the instant application, and are under examination in the instant office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants response and withdrawn.

4. Applicant's arguments filed on 22 March 2007, have been fully considered. New grounds of objection and rejection are as follows.

5. Applicant's submission of PTO-1449 listing the references AR52 and AR67 has been acknowledged and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 36 and 37 stand rejected, for reasons of record at pages 4-7, in the Office Action dated 28 December 2006.

7. Applicant argues that the claims are directed to the identification of candidate pharmacological agents to be used for the treatment of AD using the property of "protein cross-linking mediated by redox-active metals", which "play a prominent role in AD". Applicants further submit that "the agent identified by the claimed methods is a *candidate* pharmacological agent identified by an *in vitro* method", and assert that the claims do not require the identified agent necessarily exhibit an "efficacy in the in vivo treatment of AD" (pages 6-7 of Applicant's amendment dated 22 March 2007). Applicants also state that the identification of candidate agents, performed through in vitro experimentation, are typically correlated to in vivo biological experiments.

8. Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in the previous Office Action (para 16), even though redox-reactive metal catalyzed Aβ cross-linking is implicated in aggregate and plaque formation in AD, there is no evidence that inhibition of cross-linking mediated by redox-reactive metals would have a positive impact on the course of AD.

9. In making a determination of whether the application complies with the enablement requirement of 35 U.S.C. 112 first paragraph, each claimed invention must be evaluated to determine whether there is sufficient guidance provided

and supported by working examples to inform a skilled artisan how to use the claimed invention without undue experimentation. The standard of an enabling disclosure is not the ability to make and test if the invention worked but one of the ability to make and use with a reasonable expectation of success. While the skill in the art is high, the level of predictability is low. Furthermore, clinical trials to treat AD are somewhat empirical. For example, metal chelators for efficient AD treatment are still under investigation as these substances are required to cross the blood brain barrier (BBB) for effectiveness. The sole working examples in the specification, as originally filed, pertain to the copper induced aggregation of Aβ peptide in vitro, which is abolished by mannitol. While it is not necessary that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding, no extrapolation can be made of the results to use the candidate pharmacological agent in *in vivo* conditions for the treatment of AD. "[T]o be enabling, the specification..., must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Wright,* 999 F.2d at 1561, 27 USPQ2d at 1513 (emphasis added), quoted in *Genentech, Inc. v. Novo Nordisk, A/S,* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997). Thus "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed." *In re Vaeck,* 947 F.2d 488, 496 & n.23, 20 USPQ2d

1438, 1445 & n. 23 (Fed. Cir. 1991), quoted in *Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362, 1372, 52 USPQ2d 1129, 1138 (Fed. Cir. 1999).

10. "Patent protection is granted in return for an enabling disclosure..., not for vague intimations of general ideas that may or may not be workable." *Genentech,* 108 F.3d at 1365, 42 USPQ2d at 1005. "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or emplified in the specification, reasonable detail must be provided in order to enable members of the public [skilled in the art] to understand and carry out the invention." *Id.* At 1366, 42 USPQ2d at 1005 (emphasis added).

11. In view of the lack of teachings and unpredictability of the art set forth earlier, and also the total absence of the working examples, the instant specification is not found to be enabling for a method of identification of a pharmaceutical agent for the treatment of AD. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use Applicant's invention as currently claimed.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov/. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
18 May 2007

OLGA N. CHERNYSHEV, PH.D.
PRIMARY EXAMINER